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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,320	01/18/2002	H. Michael Shepard	NB 2019.00; 060925-1900	8000

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,320

Applicant(s)

SHEPARD, H. MICHAEL

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-9 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/7/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The amendment filed September 7, 2005 have been received and entered into the application.

Action Summary

The rejection of claims 1 and 23 under 35 U.S.C. 103(a) as being unpatentable over Lackey et al. (Biochemical Pharmacology, 2001) in view of Applicant's admission is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicant's arguments filed September 7, 2005 have been fully considered but they are not persuasive. Applicant argues that Lacy et al. notes that loss of tumor suppressor function and elevation or overexpression of certain genes may contribute to chemo-resistance in tumor cells overexpressing TS and Applicant does not state that functional loss of tumor suppressor genes has been linked to chemo-resistant hyperproliferative cells. This is not persuasive because Applicant admits that the function of tumor suppressor genes is major focus of recent attempts to develop innovative therapeutics for the treatment of cancer as well as the functional loss of tumor suppressor genes also has been linked to hyperproliferative inflammatory or autoimmune disease including rheumatoid arthritis. This teaching would motivate one

Art Unit: 1617

of ordinary skill in the art to employ NB1011 for the treatment of rheumatoid arthritis because the rheumatoid arthritis are related as having same cellular hyperproliferation characteristics as result of losing functions of tumor suppressor genes. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above, the Office Action of September 7, 2005 is deemed proper and asserted with full force and effect herein to obviate applicants' claims. The rejections are restated below for the Applicants' convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1617

Claims 1 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lackey et al. (Biochemical Pharmacology, 2001) in view of Applicant's admission.

Lackey et al. teach Applicant's active agent (E)-5-(2-Bromovinyl)-2'-deoxy-5'-uridyl phenyl L- methoxyalaninylphosphoramidate (also known as NB1011) has cytotoxic activity against tumor cell lines. (abstract, page 181-185, particularly, page 185 under 3.5). Lackey et al. teach on page 181 under paragraph 2.7, that NB 1011 was administered 1.25, 2.5 and 3.5 mg total dose/animal/day which is within Applicants effective dosage set forth in claims 1 and 20 as disclosed in the specification page 10, lines 1-5.

Lackey et al. do not teach the treatment of rheumatoid arthritis or an L- or D-form of NB1011.

Applicant admits on page 1, under background [0003] that the function of tumor suppressor genes is a major focus of recent attempts to develop innovative therapeutics for the treatment cancer. Applicant also admits that the functional loss of tumor suppressor genes also has been linked to hyperproliferative inflammatory or autoimmune disease including rheumatoid arthritis that have cellular hyperproliferation as one of their characteristic.

It would have been obvious to one of ordinary skill in the art to employ NB1011 for the treatment of rheumatoid arthritis because as Applicant admits that rheumatoid arthritis and cancer both have same cellular hyperproliferation characteristics and both of the disorders are related as losing functions of tumor suppressor genes.

Art Unit: 1617

One would have been motivated to employ NB1011 for the treatment of rheumatoid arthritis in order to target cellular hyperproliferation characteristics and avoid losing functions of tumor suppressor genes in rheumatoid arthritis by administering cytotoxic, antitumor (antiproliferative) compound (NB1011) as taught by Lackey.

Regarding the L- or D-compound of NB1011 is obvious since one skilled in the art expects that a compounds in general exist in more than one racemic form and selection of any one of existing racemic form of a compound is considered obvious to one of ordinary skill in the relevant art. The racemic form of a compound has been held to be within this general principal. In re Anthony, 414 F. 2d 1383, 162 USPQ 594 (CCPA 1969); Brenner v. Ladd, 247 F. Supp. 51, 147 USPQ 87 (1965).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1617

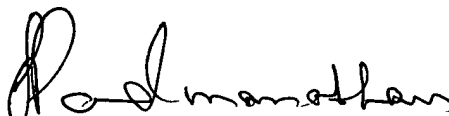
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMK
11/11/05


Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617